

107TH CONGRESS
1ST SESSION

S. 555

To amend the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services to establish a tolerance for the presence of methylmercury in seafood, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 15, 2001

Mr. LEAHY (for himself and Mr. HARKIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services to establish a tolerance for the presence of methylmercury in seafood, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Mercury-Safe Seafood
5 Act of 2001”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

1 (1) mercury pollution from coal-fired power
2 plants, waste incinerators, and other anthropogenic
3 sources continues to contaminate inland waterways
4 and territorial waters of the United States;

5 (2) mercury accumulates in fish as
6 methylmercury and is passed on to humans that eat
7 those fish;

8 (3) methylmercury is a potent neurotoxin that,
9 even in small quantities—

10 (A) can cause serious damage to the
11 human central nervous system and adverse ef-
12 fects on many other systems in the human
13 body;

14 (B) is especially harmful to pregnant
15 women and young children; and

16 (C) puts an estimated 60,000 newborns at
17 risk for adverse neurodevelopmental effects
18 each year in the United States from in utero
19 exposure;

20 (4) certain commercial seafood species can have
21 dangerously high levels of methylmercury, as evi-
22 denced by Food and Drug Administration data ac-
23 quired in the 1990's, up to the time that the agency
24 discontinued domestic sampling in 1998;

1 (5) the Food and Drug Administration’s long-
2 standing action level of 1.0 parts per million for
3 methylmercury in fish—

4 (A) is out of date; and

5 (B) according to scientific evidence, does
6 not adequately protect pregnant women and
7 young children;

8 (6) the comprehensive Mercury Study Report to
9 Congress issued by the Environmental Protection
10 Agency in December 1997 recommended a
11 methylmercury consumption limit of 0.1 micrograms
12 per kilogram of body weight per day, which is 5
13 times lower than the Food and Drug Administra-
14 tion’s current action level;

15 (7) the report entitled “Toxicological Effects of
16 Methylmercury”, issued by the National Academy of
17 Sciences in July 2000, confirmed that the Environ-
18 mental Protection Agency’s limit is “scientifically
19 justifiable for the protection of public health”;

20 (8) the report entitled “Food Safety: Federal
21 Oversight of Seafood Does Not Sufficiently Protect
22 Consumers”, issued by the General Accounting Of-
23 fice in February 2001, highlights the inadequacies of
24 Food and Drug Administration guidance regarding
25 methylmercury in commercial seafood;

1 (9) many States have been forced to issue mer-
 2 cury advisories for inland waterways and health
 3 warnings regarding the fish that may be caught in
 4 those waterways; and

5 (10) some States have also issued mercury
 6 advisories for commercial seafood.

7 **SEC. 3. TOLERANCE FOR METHYLMERCURY IN SEAFOOD.**

8 Chapter IV of the Federal Food, Drug, and Cosmetic
 9 Act (21 U.S.C. 341 et seq.) is amended—

10 (1) in section 402(a)(2), by inserting after “sec-
 11 tion 512; or” the following: “(D) if it is seafood that
 12 bears or contains methylmercury that is unsafe with-
 13 in the meaning of section 406A(a); or”; and

14 (2) by inserting after section 406 the following:

15 **“SEC. 406A. TOLERANCE FOR METHYLMERCURY IN SEA-**
 16 **FOOD.**

17 “(a) IN GENERAL.—Not later than 1 year after the
 18 date of enactment of this section, the Secretary shall by
 19 regulation establish a tolerance for the presence of
 20 methylmercury in seafood.

21 “(b) REQUIREMENTS.—The tolerance established
 22 under subsection (a) shall—

23 “(1) be based on a scientific analysis of the
 24 health risks attributable to methylmercury; and

1 “(2) be set at a level for which the Secretary
2 determines that there is a reasonable certainty that
3 no harm will result from aggregate exposure to
4 methylmercury in seafood, including all anticipated
5 dietary exposures for which there is reliable informa-
6 tion.

7 “(c) SEAFOOD DEEMED UNSAFE.—Any seafood
8 bearing or containing methylmercury shall be deemed to
9 be unsafe for purposes of section 402(a)(2)(D) unless the
10 quantity of methylmercury is within the limits of the toler-
11 ance.

12 “(d) PREGNANT WOMEN, INFANTS, AND CHIL-
13 DREN.—In establishing or modifying the tolerance under
14 subsection (a), the Secretary shall ensure that there is a
15 reasonable certainty that no harm will result to pregnant
16 women, infants, and children from aggregate exposure to
17 methylmercury.

18 “(e) SAMPLING SYSTEM.—

19 “(1) IN GENERAL.—Not later than 18 months
20 after the date of enactment of this section, the Sec-
21 retary, after consultation with the Secretary of Agri-
22 culture, shall establish a system for the collection
23 and analysis of samples of seafood to determine the
24 extent of compliance with the tolerance under sub-
25 section (a).

1 “(2) MONITORING.—The sampling system shall
 2 provide statistically valid monitoring (including mar-
 3 ket-basket studies) with respect to compliance with
 4 the tolerance.

5 “(3) AVOIDANCE OF DUPLICATION OF EF-
 6 FORT.—To the extent practicable, the sampling sys-
 7 tem shall be consistent with, and shall be coordi-
 8 nated with, other seafood sampling systems that are
 9 in use, so as to avoid duplication of effort.

10 “(f) PUBLIC EDUCATION AND ADVISORY SYSTEM.—

11 “(1) PUBLIC EDUCATION.—The Secretary, in
 12 cooperation with private and public organizations
 13 (including cooperative extension services and appro-
 14 priate State entities) shall design and implement a
 15 national public education program regarding the
 16 presence of methylmercury in seafood.

17 “(2) FEATURES.—The program shall provide—

18 “(A) information to the public regarding—

19 “(i) Federal standards and good prac-
 20 tice requirements; and

21 “(ii) promotion of public awareness,
 22 understanding, and acceptance of the
 23 standards and requirements;

24 “(B) information to health professionals so
 25 that health professionals may improve diagnosis

1 and treatment of mercury-related illness and
 2 advise individuals whose health conditions place
 3 those individuals at particular risk; and

4 “(C) such other information or advice to
 5 consumers and other persons as the Secretary
 6 determines will promote the purposes of this
 7 section.

8 “(3) HEALTH ADVISORIES.—The Secretary, in
 9 consultation with the Secretary of Agriculture and
 10 the Administrator of the Environmental Protection
 11 Agency, shall work with the States and other appro-
 12 priate entities to—

13 “(A) develop and distribute regional and
 14 national advisories concerning the presence of
 15 methylmercury in seafood;

16 “(B) develop standardized formats for
 17 written and broadcast advisories regarding
 18 methylmercury in seafood; and

19 “(C) incorporate State and local advisories
 20 into the national public education program
 21 under paragraph (1).”.

22 **SEC. 4. CONSIDERATION OF REPORT OF NATIONAL ACAD-**
 23 **EMY OF SCIENCES.**

24 In carrying out section 406A(a) of the Federal Food,
 25 Drug, and Cosmetic Act (as added by section 3), the Sec-

1 retary of Health and Human Services, acting through the
 2 Commissioner of Food and Drugs, shall consider the find-
 3 ings of the National Academy of Sciences regarding the
 4 Environmental Protection Agency's recommended level for
 5 methylmercury exposure and the presence of
 6 methylmercury in seafood, as such findings are described
 7 in the report issued by the National Academy of Sciences
 8 in July 2000.

9 **SEC. 5. AUTHORIZATION OF APPROPRIATIONS.**

10 (a) SAMPLING.—There is authorized to be appro-
 11 priated to carry out sampling under section 406A(e) of
 12 the Federal Food, Drug, and Cosmetic Act (as added by
 13 section 3) \$500,000 for each of fiscal years 2002 through
 14 2011.

15 (b) PUBLIC EDUCATION AND ADVISORY SYSTEM.—
 16 There is authorized to be appropriated to develop and im-
 17 plement the public education and advisory system under
 18 section 406A(f) of the Federal Food, Drug, and Cosmetic
 19 Act (as added by section 3) \$500,000 for each of fiscal
 20 years 2002 through 2011.

21 (c) STATE SUPPORT.—

22 (1) IN GENERAL.—There is authorized to be
 23 appropriated to support efforts of the States to sam-
 24 ple noncommercial fish and inland waterways for
 25 mercury and to produce State-specific health

1 advisories related to mercury \$2,000,000 for each of
2 fiscal years 2002 through 2011.

3 (2) **EQUITABLE DISTRIBUTION.**—The Adminis-
4 trator of the Environmental Protection Agency shall
5 distribute amounts made available under paragraph
6 (1) equitably among the States through programs in
7 existence on the date of enactment of this Act.

8 **SEC. 6. REPORT.**

9 (a) **IN GENERAL.**—Not later than 180 days after the
10 date of enactment of this Act, the Secretary of Health and
11 Human Services, acting through the Commissioner of
12 Food and Drugs, shall submit to Congress a report on
13 the progress of the Secretary in establishing the tolerance
14 required by section 406A of the Federal Food, Drug, and
15 Cosmetic Act (as added by section 3).

16 (b) **CONTENTS.**—The report shall include a descrip-
17 tion of the research that has been conducted or reviewed
18 with respect to the tolerance.

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